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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/463,276 | 05/12/2000 | Neal L. First | 96429/9085 | 6126 |

7590

09/23/2002

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 09/23/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.



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| APPLICATION NO./ CONTROL NO. | FILING DATE | FIRST NAMED INVENTOR / PATENT IN REEXAMINATION | ATTORNEY DOCKET NO. |
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| ART UNIT | PAPER |
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Commissioner of Patents and Trademarks

SEE ATTACHMENTS

File

Advisory ActionApplication No.
09/463,276Applicant(s)
First et al.Examiner
Joseph T. WeitachArt Unit
1632**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED Aug 13, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s):
See attached.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____
- Claim(s) objected to: _____
- Claim(s) rejected: 1-3 and 5-15
- Claim(s) withdrawn from consideration: _____
8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

Deborah Crouch
DEBORAH CROUCH
PRIMARY EXAMINER

GROUP 1800/630

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Section 3:

With respect to the new matter rejection made under 35 U.S.C. 112, first paragraph, amendments to claims 1 and 15 have obviated the basis of the rejection.

With respect to the art rejection made under 35 U.S.C. 102 over Barnes *et al.*, amendments to claims 12 and 15 to encompass an embryo derived from the oocyte of a bovine and the nuclear material from a species other than a bovine have obviated the basis of the rejection.

With respect to the art rejection made under 35 U.S.C. 102 over Stice *et al.*, upon reconsideration of the limitation of the term "chimeric" taught by Stice *et al.* Examiner agrees that Stice *et al.* does not teach trans-species nuclear transfer.

Section 5:

With respect to the art rejection made under 35 U.S.C. 102 over Gurdon *et al.*, Applicants argue that Gurdon teaches the difficulties of nuclear transfer in mammals and that Gurdon *et al.* does not anticipate the claims because it does not report the existence of a trans-species nuclear transfer embryo according to the amended claims. Applicants arguments are not found persuasive because while the art teaches that the difficulties of repeating results previously presented in the art, it does not clearly indicate that it would not be possible. The claims are broad encompassing the generation of a single cell embryo through nuclear transfer methods. Further, the present claims are directed to a product by process and "When the structure recited

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in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent." See MPEP 2112.01 or *In re Best*, 195 USPQ 430, 433 (CCPA 1997).

In the instant case, even if one were to accept the difficulties in repeating a set of experiments previously disclosed in the art, within the breadth of the present claims the ability to combine the nuclear material of one species into the oocyte of a bovine forming a single cell embryo would have been accomplished and thus, would anticipate the present claims.

With respect to the rejection made under 35 U.S.C. 103, Applicants point out the limitations of each of references used in the basis of the rejection. Applicants' arguments are not found persuasive because one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, it is well established in case law that a reference must be considered not only for what it expressly teaches, but also for what it fairly suggests. *In re Burkel*, 201 USPQ 67 (CCPA 1979). Furthermore, in the determination of obviousness, the state of the art as well as the level of skill of those in the art are important factors to be considered. The teaching of the cited references must be viewed in light of these factors. In the instant case, the methods for nuclear transfer were known at the time of filing. Further experiments of trans-species nuclear transfer were also conducted using a wide variety of species. It is noted that obviousness does not require absolute predictability of success; for obviousness under 35 U.S.C. § 103, all that is required is a

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reasonable expectation of success. See *In re O'Farrell*, 7 USPQ2d 1673 (CAFC 1988). In view of the combination of the teachings of the reference taken as a whole there was adequate motivation to practice the instantly claimed methods of nuclear transfer and there would have been a reasonable expectation of success to produce an embryo with said methods.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Joseph T. Woitach